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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,498	07/15/2005	Seiji Morii	TIP-05-1194	5310

35811 7590 03/14/2007  
IP GROUP OF DLA PIPER US LLP  
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PHILADELPHIA, PA 19103

EXAMINER
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OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/542,498

Applicant(s)

MORII ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/06.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

***Final Rejection***

**The Status of Claims**

Claims 1-25 are pending.

Claims 1-25 have been rejected.

**Claim Objections**

The objection of Claim 1 has been withdrawn due to the modification of the claim in the amendment.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 7 under 35 U.S.C. 112, second paragraph, has been maintained due to applicants' failure to modify the claim.

**Claim Rejections-35 USC 103**

1. Applicants' argument filed 12/13/06 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**The rejection of Claims 1-25 under 35 U.S.C. 103(a) as being unpatentable over Sakie et al ( JP3072446).**

The rejection of Claims 1-25 under 35 U.S.C. 103(a) as being unpatentable over Sakie et al ( JP3072446) has been maintained for the reasons of the record on 09/06/06.

**The rejection of Claims 1-25 under 35 U.S.C. 103(a) as being unpatentable over Sakie et al ( JP3223236).**

The rejection of Claims 1-25 under 35 U.S.C. 103(a) as being unpatentable over Sakie et al ( JP3223236) has been maintained for the reasons of the record on 09/06/06.

**Applicants' Argument**

2. Applicants argue the following issues:

- a. None of the prior art disclose adding the optically active diacyltartaric acid beforehand in the acid aqueous solution; the state of slurry of the recovered optically active diacyltartaric acid , the state of slurry of the

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recovered optically active diacyltartaric acid , the quality of the recovered optically active diacyltartaric acid, nor recycling the recovered optically active diacyltartaric acid .

The applicants' argument have been noted, but these arguments are not persuasive.

First, with respect to the first argument, the Examiner has noted applicants' argument. However, Sakie et al ( JP3072446) does disclose the preparation of dibenzoyl-D-tartaric acid in the following example 5:

106.9g of the salt of (S)-1,2-diaminopropane and dibenzoyl-D-tartaric acid having an optical purity of 91%ee was added into 250ml of water, and then stirred for 1 hour at 70°C. After addition of the salt, the mixture was cooled to 30°C, taking 5 hours. The precipitated crystal was taken out through filtration and dried to obtain 94.4g of a salt of (S)-1,2-diaminopropane and dibenzoyl-D-tartaric acid. This salt was added into 205ml of 9% hydrochloric acid aqueous solution, taking 3 hours. The mixture was stirred for 1 hour, to precipitate dibenzoyl-D-tartaric acid were collected by filtration and rinsed with water. 56g of 50% sodium hydroxide aqueous solution was added into the filtrate and the rinsing liquid for basic solution, and then distilled in atmospheric pressure to obtain 15.3g of a fraction of 115-118 °C. Water content of the obtained (S)-1,2-diaminopropane was 15%(yield 80%). The optical purity was 98%ee.

Similarly, the second Sakie et al ( JP3223236) discloses the preparation of di-p-toluoyl-D-tartaric acid in the following example 5:

99.8g of the salt of (S)-1,2-diaminopropane and di-p-toluoyl-D-tartaric acid having an optical purity of 97%ee was added into 205ml of 9% hydrochloric acid aqueous solution, taking 3 hours. After addition of the salt, the mixture was stirred for 1 hour, to precipitate di-p-toluoyl-D-tartaric acid were collected by filtration and rinsed with water. 56g of 50% sodium hydroxide aqueous solution was added into the filtrate and the rinsing liquid for basic solution, and then distilled in atmospheric pressure to obtain 15.3g of a fraction of 115-118°C. Water content of the obtained (S)-1,2-diaminopropane was 15%(yield 80%). The optical purity was 97%ee.

With respect to the optically active diacyltartaric acid being added beforehand in the acid aqueous solution, the prior art is silent . However, it has been held that merely

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reversing the order of the steps in a multi-step process is not a patentable modification absent unexpected or unobvious results. Ex Parte Rubin, 128 USPQ 440 (P.O.B.A. 1959). Cohn v. Comr .Patents, 251 F. supp. 437, 148 USPQ 486 (D.C. 1966).

Therefore, it would have been obvious to the skilled artisan in the art to be reverse the steps as an alternative so as to find out which procedure would be an optimal one.

Concerning the lack of the recycling the recovered optically active diacyltartaric acid into the optical resolution step. This is directly related to the optimization process. In order to save the time and the economy of the process, it would have been obvious to the skilled artisan in the art to recycle the recovered optically active diacyltartaric acid into the optical resolution step.

Although applicants have discussed the difference between the prior art and the claimed invention reasonably, the examiner recommends to file the declaration in which the examples of the prior art and the claimed invention are to be compared with a side-by-side format in order to present the unexpected results. Until then, the prior art are still applicable to the 103 rejection.

### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Taylor Victor Oh, MSD,LAC  
Primary Examiner  
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